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CASE STUDY

Automating the IRT Receipt Process for Temperature-Monitored Shipments

How Grünenthal leveraged Suvoda IRT to turn a long and costly manual process into a **same-day**, **automated solution**

Summary

In the clinical supply chain, accurately tracking and recording temperature-sensitive drug shipments demands accuracy and precision, as temperature excursions can put patient safety at risk. Grünenthal aimed to reduce those risks by providing better visibility into temperature-controlled shipments. By leveraging Suvoda IRT, Grünenthal automated shipment receipt processing, integrating with drug distribution and temperature data logger vendors. The results?

Same Day Solution From 29 Days

Lower Risk of Patient Drug Shortages

Automated Alerts

The Challenge

As a research and development company focused on innovative pain treatments, Grünenthal was very familiar with the frustrating delays that plagued the shipping of temperature-monitored drugs in clinical trials. Historically, the temperature management process was extremely manual, lacking overall visibility and consistency.

Upon analysis of 4,000 of its own temperature-monitored drug shipments, Grünenthal discovered that an average of 29 days elapsed while the study team obtained and evaluated data for each excursion that occurred. During that time, the drugs were quarantined and not dispensable to patients—which could potentially result in a temporary drug shortage or if sites failed to quarantine drug, a risk of accidentally dispensing drugs unfit for use.

> "Many trials involve temperature-monitored shipments, and it's critical to become immediately aware of potential excursions or missing temperature data. We wanted automation to alert clinical trial supplies managers to shipment faults, so unfit kits would not be distributed."
>
> — **Henk Dieteren,** *Senior Clinical Supply Manager, Grünenthal*

The Solution

With too much time being lost in the supply chain, Grünenthal approached Suvoda to collaborate on automating a process that would dramatically reduce the time spent responding to temperature excursions. It was clear that IRT—which governs the raising of drug shipments, handling of depot drug inventory, and registration of shipments upon receipt at site—could be the central, driving force in this first-of-its-kind automation.

Creating a Roadmap for Successful Integration

The future of the clinical supply chain depends on enabling real-time, multi-system integrations with best-in-class partners:

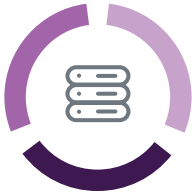
- Suvoda IRT, a modular, SaaS-based IRT that supports complex clinical trials
- Catalent® depot network, used for packaging and distributing clinical supplies
- Berlinger data loggers for monitoring shipment temperatures

In order for this multi-system integration to be successful, it was crucial to solve these 3 challenges:

Challenge
3 Different Data Models

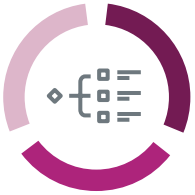
Solution
Normalize all data and terminology

Challenge
3 Different Systems



Solution
Determine data requirements up front and understand technical capabilities of each system

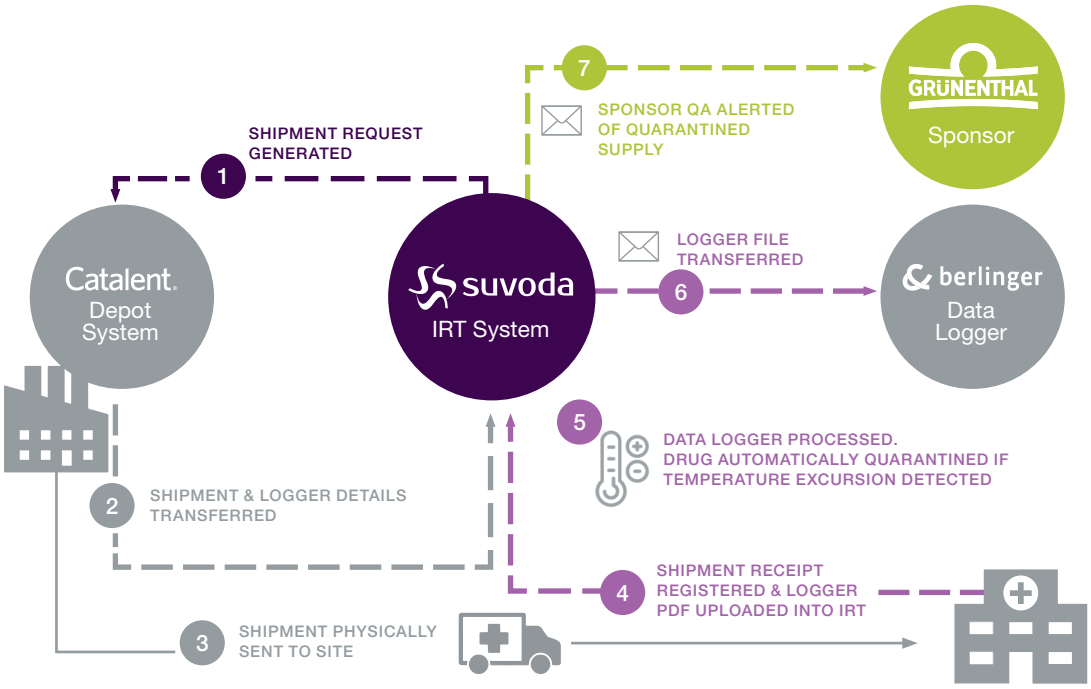
Challenge
3 Different Product Roadmaps



Solution
Carefully coordinate development and validation to ensure a long-term solution

Configuring the Automated Process

At a very high level, the movement of data was always centered around IRT, which acted as the nucleus for all drug shipment logistics from beginning to end. Suvoda IRT raised the shipments, but also needed input from Catalent on the shipment data loggers and Berlinger on excursion data.



Suvoda built a smart, predictive system that was flexible enough to handle a number of edge case scenarios such as a damaged logger, or a logger that was mistakenly excluded. With these scenarios in mind, logic was built into the system to ensure a seamless user experience and to support automation regardless of what happened in real life.

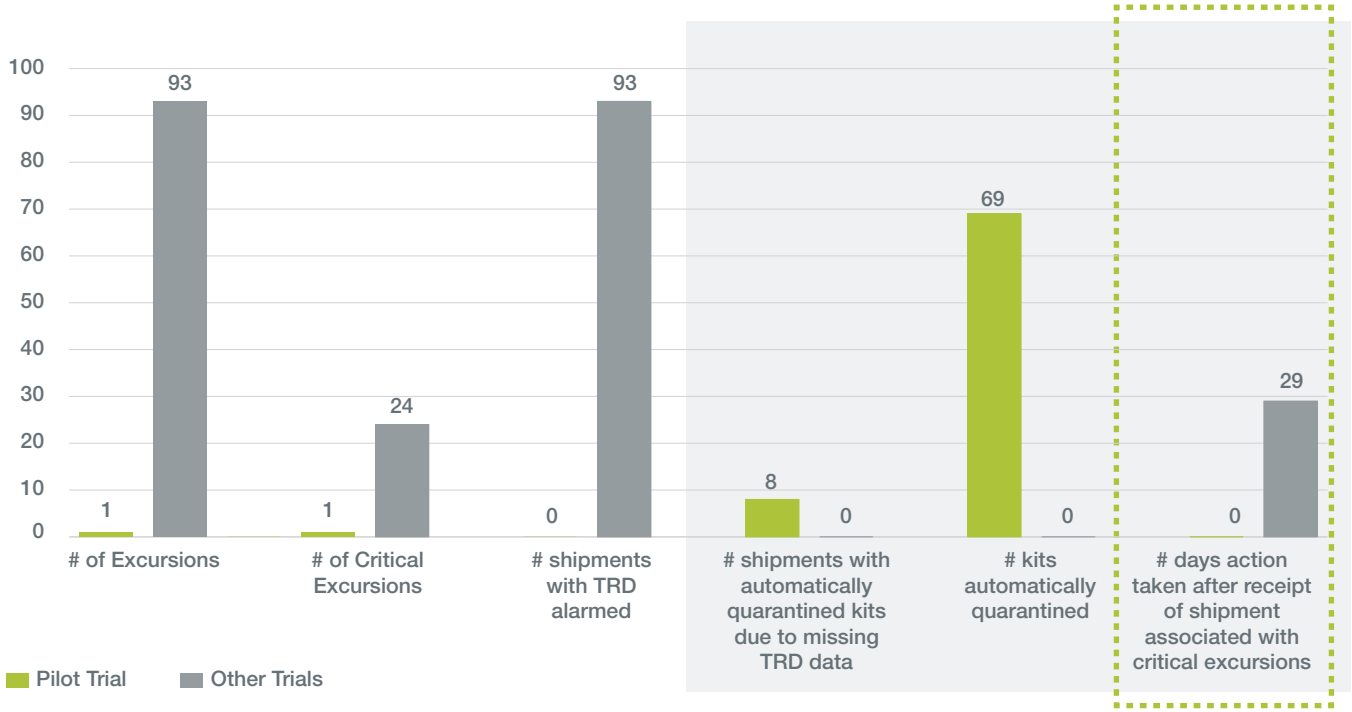
Automatic notifications generated by the IRT system kept the Grünenthal Clinical Supplies staff informed, which allowed them to streamline their excursion review process.

The Results

After conducting a 50-site pilot study utilizing this innovative integration, Grünenthal saw a significant improvement in the visibility of their temperature management process. It became a powerful demonstration of how dramatically automation can improve trials with temperature-controlled shipments. Its principal findings:

- A 29-day manual process became a **same-day solution**, helping to prevent drug shortages
- There was an **89% reduction** in shipments with automatically-quarantined kits
- It was demonstrated that process automation can ensure that World Health Organization **guidelines for ambient temperature are consistently observed**

Automation pilot results vs. Grünenthal's pre-automation shipment data



The Future of Clinical Trials

Grünenthal and Suvoda supported by a multi-partner innovative integration, demonstrated the ability of IRT to automate a critical aspect of a clinical trial: the accurate tracking and recording of drug status for high-value, high-cost, temperature-monitored drugs. The clinical trial process offers many more opportunities for automation, each holding more potential to accelerate successful outcomes for clinical trials.

For Suvoda, this successful pilot demonstrates how the company's focus on providing speed, agility, and insight into the most complex clinical trials can drive innovation for its customers. By continuing to collaborate with other patient-centric pharmaceutical and biotechnology companies equally passionate about innovating the supply chain, and by providing the best integration and project management services in the industry, Suvoda believes IRT-based automation will continue to uncover new ways of getting treatments to patients faster and more efficiently.

"Ten years ago, our industry was focused on the need for detailed drug accountability, and the role of IRT systems became more integral to the supply chain as a result. Now, leveraging IRT systems with more automation will have a similar impact on the drug development landscape."

— **Henk Dieteren,** *Senior Clinical Supply Manager, Grünenthal*

Speed, Agility, and Insight for Your Complex Clinical Trials

About Suvoda

Suvoda is an industry leading SaaS company, focused on solving complex patient randomization and clinical supply chain challenges. Founded in 2012 by experts in eClinical technologies and pioneers in IRT software, Suvoda has lead the way in standardizing IRT for innovative trial designs that require multi-system integrations. Headquartered in Conshohocken, PA, Suvoda has offices and staff around the world offering exceptional customer services and advisory services to biopharmaceutical companies of all sizes.

About the Authors

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ASSOCIATE DIRECTOR, SENIOR CLINICAL SUPPLY MANAGER, GRÜNENTHAL

Henk Dieteren is Senior Clinical Supply Manager at Grünenthal, and is primarily responsible for the support, counsel, and supervision of Grünenthal's Clinical Supply Managers in the set-up of trial-specific clinical supply concepts ensuring GMP, GDP, and GCP compliance. In addition, he focuses on continuous improvement of Grünenthal's logistical processes in clinical trial supplies. Henk commenced his work in clinical trials in 1994 for the Dutch company Tramedico, B.V., and joined Grünenthal GmbH in 2005. Since 2010, he has been working towards continuous enhancement of IRT to improve management of clinical supplies, particularly in controlled drug trials.

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Kelly Snow has spent her career in professional services and product development teams working with Top 10 Pharma companies in e-clinical focused organizations, including Phase Forward and Oracle, as well as B2C technology companies. As Vice President of Product Management & Marketing at Suvoda, she is responsible for the strategic direction of the Suvoda product suite. Kelly holds a bachelor's degree in Interdisciplinary Studies in Bioethics focusing on Neuroscience and Philosophy, a certificate in Conceptual Foundations of Medicine, and a minor in Italian Literature and Language from the University of Pittsburgh.

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Test drive?

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